

**REMARKS**

Claims 1-42 are pending. Claims 9 and 27 have been canceled. Claims 1, 11, 12, 24-26, 28-30, and 34 have been amended to clarify the subject matter regarded as the invention. Support for the amendments is found in the specification as originally filed, for example in the sequence listing as filed. Reconsideration of the pending claims in view of the comments below is respectfully requested.

**Telephonic Interview**

Applicants thank the Examiner for granting a telephonic interview on October 4, 2006. No agreement was reached during the interview. The Examiner explained her position as to why she considered the present application to be a continuation-in-part (CIP) of the parent case, notwithstanding the fact that the specification of the present case and the parent are exactly the same and that literal support for all the pending claims can be found in the parent. The Examiner also explained that it was her contention that under no circumstances would her conclusion that the present case be considered a CIP would change. Applicants strongly disagree with the arbitrary and capricious determination of the Examiner which is completely unsupported by fact or law. Applicants urge the Examiner to reconsider her position in view of the remarks below.

**Entitlement to Claim Divisional Status**

The Examiner has alleged that the present application is not entitled to claim priority to U.S. Application No. 09/575,199, (herein after "the 'parent case'"). This allegation appears based on a conclusion that the pending claims do not share sufficient similarity to the claims of the parent case. Based upon this, the Examiner has concluded that the present application is to be regarded as a continuation-in-part as opposed to a divisional. This position is incorrect as a matter of procedure, fact, and as a matter of law.

The Examiner may require an application which claims two or more independent and distinct inventions to be restricted to one of the inventions. 35 U.S.C. § 121. If the other invention is made the subject of a divisional application which complies with the requirements of 35 U.S.C. §

120, “it shall be entitled to the benefit of the filing date of the original application.” *Id.* (Emphasis added).

To claim the benefit of priority under section 120, a patent application must meet four criteria. First, the child case must satisfy the requirements provided by the first paragraph of 35 U.S.C. 112. Second, the parent and child cases must share at least one common inventor. Third, the child case must be filed while the parent case is still pending. Fourth, a reference to the parent case must be added to the child application. If these three requirements are met, the subsequent application is “entitled to the benefit of the filing date of the first application . . . .” 35 U.S.C. § 120.

The M.P.E.P., which does not have the force of law, provides further guidance to examiners regarding how to deal with divisional applications.

“A later application for an independent or distinct invention, carved out of a pending application and disclosing and claiming only subject matter disclosed in the earlier or parent application, is known as a divisional application or “division.” A divisional application is often filed as a result of a restriction requirement made by the examiner. The divisional application must claim the benefit of the prior nonprovisional application under 35 U.S.C. 121 or 365(c). See MPEP § 201.11 for the conditions for receiving the benefit of the filing date of the prior application. The divisional application should set forth at least the portion of the earlier disclosure that is germane to the invention as claimed in the divisional application.” M.P.E.P. § 201.06.

The parent case was filed with 74 claims on May 18, 2000. The Examiner imposed a Restriction Requirement on January 24, 2002, which divided the claim set into seven different groups. Applicants elected to pursue the claims of Group I, claims 1-27 and 28-34. The present divisional application seeks to prosecute the inventions that were withdrawn in view of this Restriction Requirement. This application is entitled by statutory right under 35 U.S.C. § 121 to claim priority to the parent application

The present divisional application satisfies the four requirements of 35 U.S.C. 120. First, the subject matter of the pending claims satisfies the requirements of Applicants have disclosed the subject matter of the pending claims as required by the first paragraph of 35 U.S.C. 112. Specifically, the claims enjoy adequate written support, are fully enabled, and the application discloses the best mode for practicing the claimed invention at the time the application was filed.

Second, the present divisional application and the parent case share the same named inventors. Third, the two cases were co-pending at the time the divisional application was filed because the divisional application was filed on December 21, 2003, while the parent case went abandoned for failure to timely respond to a final Office Action mailed on April 13, 2004. Fourth and finally, by way of the preliminary amendment filed on with the divisional application, the specification of the present case was amended to recite a proper claim for priority to the parent case. In view of this showing it is clear that the present case is properly entitled to claim priority to the parent case.

### **Priority and Oath/Declaration**

The Examiner has alleged that pending claims 1-42 do not “correspond” to any of the claims originally filed in the parent case. Based on this, the Examiner considers the present case a “continuation-in-part,” and has required that Applicants submit a supplemental oath or declaration. Office Action, page 2. The Examiner has further stated that “even if the instant claims are amended to correspond to those of the parent application,” the present case will be still be considered a continuation-in-part. The Examiner’s position was reiterated during the telephonic interview held on October 4th. The Examiner lacks the authority to make this determination as there is no language in the statute, the rules, or even in the M.P.E.P. that supports this procedure.

Applicants also traverse the Examiner’s position that a determination of whether an application contains new matter can be based on whether the claims of a daughter case “correspond” to the claims pending in the parent. Instead, the proper new matter analysis turns on whether the language of the claims in the daughter case are adequately supported by the specification of the parent case. Here, literal support for the pending claims is present in the parent case. A claim chart provide some examples of this support is provided with this Response as Appendix A. In view of the support provided for the pending claims present in the parent case, the Examiner’s arbitrary and capricious conclusion that the pending claims contain new matter is clearly and unambiguously in error and should be withdrawn.

The Examiner has alleged that the subject matter of the pending claims is not sufficiently similar to the restricted claims of the parent case to enjoy divisional status. However, the Office Action cites no authority in support of this position. Neither the statute, the rules of patent practice,

or the M.P.E.P. require that claims in a divisional application use the exact language of the claims from the parent case. All that is required is that the divisional application carves out an independent and distinct invention that was claims but not prosecuted in the parent case. Here, even the Examiner admits that the pending claims show “show some similarity to claims 35-64 of [the] parent application.” Office Action, page 2. And while the Office Action notes that claim 35 of the parent case required “at least two dimers,” the Office Action failed to observe that other claims, such as independent claim 54 and other claims in the parent case do not make such a requirement. Applicants submit that the pending claims fall squarely within the four corners of the subject matter withdrawn from the parent case. Applicants further submit that, in view of the showing discussed above regarding the requirements of a divisional application, that the burden lies squarely on the Examiner’s shoulders to show why the pending claims are not entitled to claim divisional status to the parent case.

Even if the Examiner were to somehow manage the Herculean feat of establishing a prima facie case that the pending claims did not read on an invention previously claimed by the parent case, (which she cannot), the proper course of action is to consider the present case a continuation, as opposed to a continuation-in-part. The CCPA spoke directly to the issue of how the Examiner was supposed to handle a question of new matter in claims added to an application. “Broadening a claim does not add new matter to the disclosure. Disclosure is that which is taught, not that which is claimed. An applicant is entitled to claims as broad as the prior art and his disclosure will allow.” *In re Rasmussen*, 650 F.2d 1212, 211 USPQ 323 (CCPA 1981). Determining whether the claims of the parent case are outside the scope of the present disclosure or that of the parent case, of which it is a copy, requires that the Examiner look at the entire disclosure and not merely the claims of the parent case. In the event the Examiner considers the claims subject matter to lack written support in the specification as filed, it should reject the claims not as new matter by deeming the present case a continuation-in-part. Instead, the Examiner should merely reject the pending claims under 35 U.S.C. 112, first paragraph. This is the proper procedure.

The Examiner requested that support in the specification be provided for the pending claims. In response, Applicants provide the table in Appendix A, which provides a detailed review of the pending claims and provides numerous examples of support for those claims in the parent case as

originally filed. This evidence more than satisfies Applicants' duty to find written support for the pending claims. Applicants also note for the record that the table provide is not exhaustive but yet is more than sufficient to overcome the Examiner's position.

In view of this, Applicants respectfully submit that the requirement for a supplemental oath or declaration has been traversed and that this requirement should be withdrawn.

### **The Pending Claims are Enabled**

Claims 1-42 stand rejected under 35 U.S.C. § 112, first paragraph, for allegedly failing to comply with the enablement requirement. "To be enabling, the specification of a patent must teach those skilled in the art to make and use the full scope of the claimed invention without 'undue experimentation' ... Nothing more than objective enablement is required, and therefore it is irrelevant whether this teaching is provided through broad terminology or illustrative examples." *In re Wright*, 999 F.2d 1557, 1561 (Fed. Cir. 1993).

Here, the Examiner has alleged that the specification does not enable the production of VEGF dimers with a Cys at 116 or an Asn75Glu substitution. The recombinant expression of mutated proteins containing single amino acid substitutions such as those described above was notoriously well known in the art at the relevant time period. This point is illustrated by the work of Gibbs, et al. (J. Biol. Chem. (1996) 271:28710-28716), which describes the generation of mutant proteins. In view of this showing it is clear that one of ordinary skill in the art could readily prepare VEGF dimers with a Cys at 116 of SEQ ID NO:1 or an Asn to Glu amino acid substitution at position 75 of SEQ ID NO:1 without undue experimentation. In view of the showing of the state of the art at the time the present application was filed, it is clear that the Examiner has failed to make a prima facie argument regarding the alleged lack of enablement. As such, the present rejection should be withdrawn.

### **The Pending Claims are Definite and Particular**

The Examiner rejected claims 1-42 alleging that the claims were indefinite. Applicants have amended the claims to address the issues raised by the Examiner regarding the sequence identification numbers. As such, this reason for the rejection has been overcome.

The Examiner alleged that the language “corresponding to” a particular position in SEQ ID NO: 2 was indefinite. The Examiner must not realize that VEGF is produced with a linker sequence which is cleaved and that there are a number of forms of VEGF, as discussed in the specification at page 1, lines 13 to 29. The language “corresponding to” a particular position in the prototype sequence was provided to make clear which Cys or Asn residue was being referenced in the claim. Applicants have removed the language complained of by the Examiner and note that the scope and intent of the claim remains unaltered in spite of this amendment.

Claims 11, 12, and 28 have been amended to clarify the subject matter of the invention and simultaneously address the issues raised by the Examiner. In view of these amendments, the issues raised in the Office Action have been overcome.

#### **The Pending Claims are Novel**

Claims 1-5, 10-16, and 20-21 stand rejected under 35 U.S.C. § 102(e), as allegedly being anticipated by Alitalo, et al., U.S. Patent No. 6,965,010, which was filed on February 26, 2001 and claims priority to two provisional applications, 60/205,331 and 60/185,205, filed May 18, 2000 and Feb. 25, 2000, respectively. Neither of these applications was filed before the provisional applications from which the present case claims the benefit of priority. As such, the Alitalo, et al. reference is not available as prior art against the presently pending claims. Accordingly, the present rejection should be withdrawn.

**CONCLUSION**

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the event the U.S. Patent and Trademark office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to Deposit Account No. 03-1952 referencing docket no. 219002031111. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

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Respectfully submitted,

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